Short-Term Clinical Follow-up of Screw Fixation in Foot and Ankle Procedures

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INTRODUCTION: To provide greater optionality and performance for the treatment of a variety of foot and ankle procedures, the Paragon28® Monster® Screw System offers an array of instrumentation and implants specifically designed to accommodate bone reconstruction, arthrodesis, ligament fixation, and/or fracture repair for the foot and ankle. Procedures that can be completed with these systems, include but are not limited to, 5th metatarsal fracture fixation, Lisfranc repair, calcaneal slide osteotomy, and/or subtalar arthrodesis. The clinical efficacy of certain devices of the system has been studied[1-3], however no studies have evaluated the collective system. Additionally, new EU medical device regulations require relevant clinical data, therefore the purpose of this research was to evaluate the safety, performance, and clinical benefit of the Paragon 28® Monster® Screw System as assessed by device-related adverse events and union rate.

METHODS: This was an ambispective, single-site, multi-surgeon, consecutive case clinical study. After gaining institutional review board approval, retrospective data was analyzed from consecutive patients who were under the care of one of the four participating investigators and were implanted with at least one device from the Monster® Screw System. Any patients that had undergone a foot and/or ankle procedure involving bone reconstruction/osteotomy, arthrodesis/joint fusion, ligament fixation, and/or fracture repair/fixation using an implant from the Monster® Screw System and had a minimum of 3 months of clinical and radiographic follow-up were included. The devices included in this study were Mini-Monster® cannulated and solid screws, Monster® hindfoot screws, Joust® beaming screws, Monster® BITE snap-off screws, and PRECISION® Jones Fracture Screws (Table 1).

RESULTS SECTION: A total of 81 patients with an average age of 54.2 years old and Body Mass Index (BMI) of 32.2 were retrospectively reviewed. The average length of clinical follow-up was 5.4 months and 59 out of 81 patients (72.0%), underwent concurrent procedures. At the final follow-up, 80 of the 81 eligible patients did not experience any device related serious adverse events, thereby successfully meeting the primary endpoint of the study. There were four instances of delayed union or non-union (4.9%), one instance of loss of correction at final follow-up (1.2%), and one adverse event related to the device (1.2%). Three of the four cases (75%) with delayed or nonunion were for fracture fixation (Table 2). The related adverse event was loosening of a snap-off screw. This adverse event was resolved with surgical removal of the screw.

DISCUSSION: In summary, 80 out of 81 patients (98.8%) who were implanted with at least one device from the screw system under study successfully met the primary endpoint of the study. In total, there were four instances of delayed or nonunion (4.9%), one instance of loss of correction at final follow-up (1.2%), and one adverse event related to the device (1.2%), which was resolved surgically. Strengths of this study include a large, realistic sample size, which was intentionally built into the study design with the broad inclusion criteria and lack of exclusion criteria. The resultant patient population had many comorbidities, with over half of population being current/former smokers (60.5%) and the average BMI was 32.2. Half of the patients that had non-union and the one patient with a device related adverse event were former smokers. However, there are inherent shortcomings associated with retrospective data collection and although our study population attempts to represent the demographics of a realistic patient population, all patients came from the same geographic regions, thus the population in this study may not adequately reflect the overall population as a whole.

SIGNIFICANCE/CLINICAL RELEVANCE: The study results support that the Monster® Screw System is safe and effective for bone reconstruction, joint fusion, ligament fixation, and fracture repair in the foot and ankle.

REFERENCES: [1] Heifner 2022, [2] So 2018, [3] Wagner 2018

Table 1: Index Device Indications and Location.

System	Bone Reconstruction/ Osteotomy	Arthrodesis/ Joint Fusion	Ligament Fixation	Fracture Repair/ Fixation	Foot	Ankle
Mini-Monster® Cannulated Screw	16	1	7	41	38	27
Mini-Monster® Solid Screw	10	0	0	1	10	1
Monster® Hindfoot Screw	6	15	0	3	20	4
Joust® Beaming Screw	0	3	0	0	3	0
Monster® BITE Snap-off Screw	22	1	0	0	23	0
PRECISION® Jones Fracture Screw	0	0	0	6	6	0
Total	**54**	**20**	**7**	**51**	**100**	**32**

Table 2: Characteristics of Patients with Delayed or Nonunion.

Patient Number	Union Status	Gender	BMI	Age	Smoking Status	Indication(s)
01	Delayed	Female	29	59	Former	Fracture Repair/Fixation
04	Nonunion	Male	31	63	Former	Fracture Repair/Fixation
09	Nonunion	Female	48	54	Non-Smoker	Bone Reconstruction/Osteotomy, Arthrodesis/Joint Fusion
78	Nonunion	Male	41	23	Non-Smoker	Fracture Repair/Fixation